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REMARKSClaim Rejections under 35 U.S.C. § 103(a)

The Examiner has rejected claims 1-6 for as being unpatentable over Newman et al. (U.S. Patent No. 5,954,713), stating that although "Newman et al. do not explicitly recite a flow valve it would be obvious ... to modify the invention of Newman et al. to include a flow valve, ...for it is **necessary** to control the flow..." See p. 4 of the Office Action. As herein amended, claim 1 requires, among other elements, a grasping device *"for removing blockage from a blood vessel."* Emphasis added.

Applicants respectfully submit that Newman alone, and Newman in combination with Matsui and/or Deaton do not render the claimed subject matter obvious. The presently claimed endarterectomy is an endoscopic instrument with valve control of the gas on the handle, and a plaque-removing instrument having a grasping device for removing blockage from a blood vessel, as a stand-alone instrument. No separate cutting tool, forceps, grasping device or instrument is required to remove blockage from the blood vessel into which the endarterectomy is inserted. As outlined below, there is no suggestion in Newman, Newman with Matsui, or Newman with Matsui and Deaton to modify any of the instruments disclosed in the cited references to arrive at the claimed instrument, wherein endoscopic technology, fluid-delivery capability, controlled gas delivery, and blockage removal capability are all present in a single instrument.

A. Newman has neither the controlled gas delivery element nor the capability to remove blockage from the artery by the endoscope itself. Newman clearly states, in col. 5, line 66 through col. 6, line 15 that "the plaque build-up ... are removed ...by pulling the plaque build-up out through the incision with forceps" or "If necessary ... a surgical [cutting] instrument, such as the ones illustrated in FIGS. 7A, 7B, 7C and 8 can be

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inserted and the plaque build-up is pulled out through the insertion by the surgical cutting instrument or with forceps.”

B. Matsui relates to an “apparatus for performing treating operation in a body cavity of a patient with the use of treating tools in combination with an endoscope” (see Abstract) and is too large to remove plaque in a blood vessel, nor is there any suggestion it could be modified for use in such a manner. The entire disclosure and claims are directed towards an apparatus that can guide an endoscope and treating tools (i.e. surgical tools, such as clamps, suturing tools, cutting tools, and the like - see FIGS. 7-33) for performing “treating operation in a body cavity.” See claim 1, and col. 1, line 53 through col. 2, line 1 (“the present invention provides an endoscopic surgery apparatus for performing treatment operation on a diseased region in a body cavity ... and ... using treating tools in combination with the endoscope...”). The suggestion to combine the grasping element of Matsui with the endoscope of Newman is not present because Matsui covers an entirely different area of surgery and the grasping device is for holding tissue to allow surgical procedures to take place within a body cavity, not for grasping a thin layer of plaque build-up within an artery so as to remove the plaque build-up.

C. Combining Deaton still does not provide the necessary suggestion for combination. Applicants respectfully submit that, in spite of the Examiner’s continued assertion that element 100 is a grasping device, there is no grasping device disclosed in Deaton for removal of blockage within a blood vessel. Element 100 is repeatedly referred to in Deaton et al. as a flexible blade dissector (see col. 4, lines 8-9 and lines 16-17; col. 6, lines 36-37; col. 7, lines 38; col. 10, lines 44-45, and col. 13, line 1, among other places). Further, Deaton distinguishes element 100 from a grasping device by stating in col. 5, lines 13-15 that “Alternatively, the lumen 110 may be used for insertion

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of other instruments, such as an endoscope, a cutter, a snare, a *grasper* or other tool.” Emphasis added. Further, as defined in The American Heritage Dictionary, “to grasp” means to take hold of or seize firmly with or as if with the hand” and as disclosed and claimed in the present application, a grasping device includes a hook or a barb. Applicants respectfully submit that flexible blade dissector 100 of Deaton et al. is not a grasping device, and is especially neither a barb nor a hook.

Moreover, as stated in col. 6, lines 15-40, flexible dissector blade 100 functions to separate the plaque and endothelial layer away from the medial layer of an artery (or other blood vessel) by creating a plane of separation between the plaque and media layer or between the medial and adventitial layers of the artery. This is functionally equivalent to the separation of these layers caused by the injection of gas and fluid between such layers in the presently claimed invention. Flexible blade dissector 100 does not remove the plaque - it merely dissects and separates it from core of the artery.

Finally, Deaton et al. clearly state that removal of the plaque within the arterial lumen after it is cut loose by flexible blade dissector 100 occurs separately (see col. 3, lines 47-52; col. 7, lines 18-23 “Once the plaque has been freed ... the plaque is removed from the arterial lumen, using known techniques.” In fact, as claimed and disclosed throughout Deaton et al. (see col. 7, line 66 through col. 8, line 14, and claims 20-24, for example), *at least* two flexible blade dissectors, and possibly more, are actually required to completely free the plaque from within an artery or blood vessel - the first to create the plane of separation as it progresses and the second to widen the plane to completely free the plaque (and any accompanying medial layer) within the artery. To quote: “In use, the first flexible blade dissector 100 is advanced ... so that the first flexible dissecting blade 102 creates a first, narrow channel along the plane of separation between the plaque

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and the medial layer. Next, the second flexible blade dissector 150 is advanced ... so that the ... second flexible dissecting blade 152 widens the channel. ... This process may be continued with any *additional coaxial flexible blade dissectors*, if necessary, until the plaque has been freed from the entire inner circumference of the arterial lumen.” *Id.* Emphasis added. Moreover, after completely freeing the plaque using two dissector blades, additional instruments and techniques are actually required to remove the plaque from the artery itself (not just remove it away from the interstitia layer), including a cutting device to termination the plane of separation (see col. 7, lines 23-25 “the method may utilize a separate device, such as a Moll Ring Cutter (U.S. Patent. No. 5,843,102) to terminate the plane of separation.”). In short, the endoscopic apparatus of Deaton et al. would not be combined with Newman and Matsue to arrive at all the elements of the presently claimed subject matter - a requirement for an obviousness rejection - because Deaton et al. discloses an endoscopic device that functions differently, and like all the reference cited, requires more than one device to actually perform the endarterectomy. All three references disclose and claim endoscopic devices that lack required elements as claimed in claim 1 of the present application, and in use, require separate and multiple devices to perform an endarterectomy, or in the case of Matsui, are not designed to perform an endarterectomy. There is no suggestion in any of Newman, Matsui or Deaton to eliminate elements to simplify, improve, or increase efficiency and successful use of the disclosed devices, or to combine their features with those of other devices to arrive at the very elegant all-in-one device of the presently claimed subject matter. Therefore, Applicants respectfully submit that Newman does not render the presently claimed subject matter obvious, whether alone or in combination with Matsui and Deaton.

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As presented previously in Response A, obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention unless there was some teaching, suggestion, or incentive in the prior art which would have made such a combination appropriate. See *e.g. Ashland Oil v. Delta Resins and Refractories, Inc.*, 766 F.2d 281 at 293 (Fed. Cir. 1985). One cannot argue obviousness based on the advantage of hindsight. The suggestion and motivation for a modification or combination must be present in the art itself, or the knowledge generally available in the field. The Examiner has provided no reference that teaches, or suggests modifying or combining references, which will lead to the claimed invention, which is a single instrument for performing an endarterectomy that requires a flow valve built into the handle of the instrument itself and a grasping device for separating and removing blockage in a blood vessel. As such, there is no *prima facie* case for obviousness.

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CONCLUSION

For the reasons set forth above, it is submitted that all pending claims are in condition for allowance. Reconsideration of the claims and a notice of allowance are therefore requested. Please charge deposit account number 19-4972 for any applicable fees required for timely submission of this response. Applicants do not believe an extension of time is required. However, in the event that an extension of time has been overlooked, Applicants submit this conditional petition for an extension of time, and request that deposit account number 19-4972 be charged for any additional fees that may be required for the timely consideration of this application. The Examiner is requested to telephone the undersigned if any matters remain outstanding so that they may be resolved expeditiously.

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Respectfully submitted,



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